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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,211

09/09/2003

Brian Kelleher

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MERLE W. RICHMAN, III

P.O. BOX 3333

LA JOLLA, CA 92038

EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,211	<b>Applicant(s)</b> KELLEHER ET AL.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 22-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/28/04 5/2/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Invention I and Species C, D, and L (claims 1-21) in the reply filed on March 20, 2008 is acknowledged.

This is the initial Office Action based on the 10/659211 application filed September 9, 2003. Claims 1-21 as elected are currently pending and considered below.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

3. Claim 9 recites the limitation "the innermost layer smoothing or manipulation step" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim when dependent from claim 1 or claim 7.
4. Claim 17 recites the limitation "said two regions of the organ wall" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 18 and 20 further recite this limitation and are also objected to.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5 and 8-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 5 recites the limitation "the step of creating a gap" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. The examiner notes that claim 4, from which claim 5 depends recites the limitation "further comprising means for creating a gap" but it does not positively recite the step of creating a gap. Further, because claims 8-12, and 15-21 depend either directly or indirectly, at least in part, from claim 5, they are also rejected under U.S.C. 112, second paragraph.

8. Claims 13 and 14 recite the limitation "the gap" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim. The examiner notes that claim 4, from which claims 13 and 14 depend recites the limitation "further comprising means for creating a gap" but it does not positively recite a gap.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-9 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPub 2003/0109892 A1 to Deem et al.

Regarding the above claims, Deem et al teach either the method of or a device capable of the method of the claims as follows. Deem et al teach a device which is deployed into smoothed stomach tissue from the interior of the stomach, which creates a partition or pouch in the stomach by bringing together two separate portions of the interior lumen of the organ and fastened by staples, sutures, or other biologically

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compatible materials. (See Figures 23A-23D and Paragraphs [0128]-[0129]) Further, the device shown would be capable of retracting the stomach wall away from extra-luminal organs (as in claims 4 and 5) to create a gap of the dimensions called for in claims 13 and 14. Although Deem et al do not explicitly show or disclose that the device is used in layers other than the innermost lining of the stomach, the examiner believes it would have been obvious to one having ordinary skill in the art to simply penetrate further into the tissue of the organ in order to obtain a more stable grasp of the organ wall and therefore create a more stable partition or pouch. Further, the process of repeating steps in order to create more sutures would have been obvious to one having ordinary skill in the art at the time the invention was made in order to create a pouch or partition of the appropriate size, shape, and length.

13. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al in view of USPN 7,297,150 B2 to Cartledge et al.

Deem et al teach the method of claims 1, 2, 3, 5, and 7 as described above, however they fail to teach or disclose the use of impedance to determine placement of the tissue-contacting portion of the device. Cartledge et al disclose a device for use in controlling the diameter of a lumen or luminal organ which uses the impedance of tissue to determine whether it is the proper tissue in which to implant the device (Col. 11, lines 54-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the impedance measurement of Cartledge et al to the partitioning device of Deem et al in order to ensure that the tissue-gripping portions were penetrating the proper layer and type of tissue.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPGPub 2004/0210243 A1 to Gannoe et al and USPN 6,071,292 to Makower et al disclose limitations of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763